CLAIMS

What is claimed is:

1. Method of determining the dissolution rate of an analyte in a non-aqueous liquid composition, comprising the steps of:
   (a) providing a non-aqueous liquid composition comprising an analyte and a non-aqueous base;
   (b) adding a non-aqueous diluent to the non-aqueous liquid composition to provide a diluted non-aqueous liquid composition;
   (c) introducing at least part of the diluted non-aqueous liquid composition and an aqueous dissolution medium into a dissolution testing apparatus;
   (d) contacting the diluted non-aqueous liquid composition and the aqueous dissolution medium for a predetermined time; and
   (e) determining the amount of analyte in the aqueous dissolution medium.

2. The method of claim 1, wherein the amount of analyte in the aqueous dissolution medium is determined at several different predetermined times.

3. The method of claim 1, further including, in step (e), a step of filtering the aqueous dissolution medium, which is to be used for determining the amount of analyte in the aqueous dissolution medium, before determining the amount of analyte therein.

4. The method of claim 3, wherein the pore size of the filter ranges from about 0.1 to about 50 microns.

5. The method of claim 1, wherein the non-aqueous liquid composition is a pharmaceutical composition.

6. The method of claim 5, wherein the analyte is the pharmaceutically active component.

7. The method of claim 5, wherein the pharmaceutical composition is a sustained release dosage form.

8. The method of claim 5, wherein the pharmaceutical composition further contains pharmaceutically acceptable components selected from the group consisting of excipients, additives, suspending agents, preservatives, wetting agents, thickeners, buffers, flocculating agents, flavoring agents, sweeteners, colorants and fragrances.

9. The method of claim 1, wherein the analyte is selected from the group consisting of ACE inhibitor; α-adrenergic agonist; β-adrenergic agonist; α-adrenergic blocker; β-adrenergic blocker; alcohol deterrent; aldose reductase inhibitor; aldosterone antagonist; amino acid; anabolic; analgesic; anesthetic; anorexic; antacid; anthelmintic; antiacne agent; antiallergic; antiandrogen; antianginal agent; antianxiety agent; antiarrythmic; antiasthmatic; antibacterial agent; antialopecia and antibaldness agent; antiamebic; antibody; anticholinergic drug; anticoagulant; blood thinner; anticolitis drug; anticonvulsant; anticystitis drug; antidepressant; antidiabetic agent; antidiarrheal; antidiuretic; antidote; antiemetic; antiestrogen; antiflatulent; antifungal agent; antigen; antiglaucoma agent; antihistaminic; antihyperactive; antihyperlipoproteinemic; antihypertensive; antihyperthyroid agent; antihypotensive; antihypothyroid agent; anti-infective; anti-inflammatory agent; antimalarial agent; antimigraine agent; antineoplastic; antiobesity agent; antiparkinsonian agent; antidyskinetics; antipneumonia agent; antiprotozoal agent; antipruritic; antipsoriatic; antipsychotic; antipyretic; antirheumatic; antisecretory agent; anti-shock agent; antispasmodic; antithrombotic; antitumor agent; antitussive; antiulcerative; antiviral agent; anxiolytic; bactericidin; bone densifier; bronchodilator; calcium channel blocker; carbonic anhydrase inhibitor; cardiotonic; heart stimulant; chemotherapeutic; choleretic; cholinergic; CNS stimulant; coagulant; contraceptive; cystic fibrosis drug; decongestant; diuretic; dopamine receptor agonist; dopamine receptor antagonist; enzyme; estrogen; expectorant; glucocorticoid; hemostatics; HMG CoA reductase inhibitor; hypnotic; immunomodulator; immunosuppressant; laxative; miotic; monoamine oxidase inhibitor; mucolytic; muscle relaxant; mydriatic; narcotic antagonist; NMDA receptor antagonist; oligonucleotide; ophthalmic drug; oxytocic; peptide; proteins; polysaccharide; progestogen; prostaglandin; protease inhibitor; respiratory stimulant; sedative; serotonin uptake inhibitor; sex hormone; smoking cessation drug; smooth muscle relaxant; smooth

muscle stimulant; thrombolytic; tranquilizer; urinary acidifier; vasodilators; and vasoprotectant.

10. The method of claim 1, wherein the analyte is a cephalosporin selected from the group consisting of ceftiofur, cefepime, cefixime, cefoperazone, cefotaxime, cefpodoxime, ceftazidime, ceftizoxime, ceftriaxone, moxalactam, pharmaceutically acceptable salts and derivatives thereof.

11. The method of claim 10, wherein the analyte is ceftiofur, a pharmaceutically acceptable salt or derivative thereof.

12. The method of claim 1, wherein the non-aqueous base is selected from a fat or wax.

13. The method of claim 12, wherein the non-aqueous base is a fat that is an oil.

14. The method of claim 13, wherein the oil is selected from the group consisting of canola oil, coconut oil, corn oil, peanut oil, sesame oil, olive oil, palm oil, safflower oil, soybean oil, cottonseed oil, rapeseed oil, sunflower oil and mixtures thereof.

15. The method of claim 12, wherein the oil is cottonseed oil.

16. The method of claim 1, wherein the non-aqueous liquid composition is a suspension, solution or emulsion.

17. The method of claim 1, wherein the non-aqueous liquid composition is a suspension.

18. The method of claim 1, wherein the non-aqueous diluent is selected from the group consisting of oils and organic solvents.

19. The method of claim 18, wherein the non-aqueous diluent is an oil.

20. The method of claim 19, wherein the oil is coconut oil or cottonseed oil.

21. The method of claim 1, wherein the amount of non-aqueous diluent is from about 0.25 to about 10 parts by weight relative to the amount of non-aqueous liquid composition.

22. The method of claim 1, wherein the contacting is conducted for a predetermined time to dissolve from about 10% to about 100% of the total amount of analyte, which was initially present in the non-aqueous liquid composition, in the aqueous dissolution medium.

23. The method of claim 22, wherein the stirring is conducted for a predetermined time to dissolve from about 10% to about 100% of the total amount of analyte, which was initially present in the non-aqueous liquid composition, in the aqueous dissolution medium.

24. The method of claim 1, wherein the aqueous dissolution medium is prepared using high purity water.

25. The method of claim 1, wherein the aqueous dissolution medium is selected from a group consisting of water, hydrochloric acid solution, simulated gastric fluid, buffer solution, simulated intestinal fluid, water containing a surfactant, buffer solution containing a surfactant, and aqueous alcoholic solution.

26. The method of claim 25, wherein the aqueous dissolution medium is a buffer solution.

27. The method of claim 26, wherein the buffer solution is selected from the group consisting of glycine buffer at pH ranging from 2 to 3, citrate buffer at pH 3, acetate buffer at pH ranging from 4 to 5, acetate buffer in normal saline at pH 5.5, phosphate buffer at pH ranging from 6 to 8, potassium free phosphate buffer at pH 6.8, phosphate buffer in normal saline at pH 7.4, and borate buffer at pH ranging from 8 to 10 .

28. The method of claim 27, wherein the buffer solution has a molarity of from about 1 mM to about 10 mM.

29. The method of claim 27, wherein the buffer has a molarity of from about 1 mM to about 5 mM.

30. The method of claim 1, wherein in step (d) the ratio of non-aqueous liquid composition to aqueous dissolution medium is from about 1 : 2,000 to about 1 : 100,000 by volume.

31. The method of claim 30, wherein in step (d) the ratio of the diluted non-aqueous liquid composition to the aqueous dissolution medium is from about 1 : 5,000 to about 1 : 40,000 by volume.

32. The method of claim 1, wherein the dissolution testing apparatus is a paddle assembly.

33. Method of determining the dissolution rate of an analyte in a non-aqueous liquid composition, comprising the steps of:

(a) providing a non-aqueous liquid composition comprising an analyte and a non-aqueous base;

(b) introducing at least part of the non-aqueous liquid composition and an aqueous dissolution medium into a dissolution testing apparatus, wherein the aqueous dissolution medium comprises a buffer having a molarity of from about 1 mM to about 10 mM;

(c) contacting the non-aqueous liquid composition and the aqueous dissolution medium for a predetermined time; and

(d) determining the amount of analyte in the aqueous dissolution medium.

34. Method of determining the dissolution rate of an analyte in a non-aqueous liquid composition, comprising the steps of:

(a) providing a non-aqueous liquid composition comprising an analyte and a non-aqueous base;

(b) introducing at least part of the non-aqueous liquid composition and an aqueous dissolution medium into a dissolution testing apparatus, wherein the volume ratio of non-aqueous liquid composition to aqueous dissolution medium in the dissolution testing apparatus is from about 1 : 2,000 to about 1 : 100,000;

(c) contacting the non-aqueous liquid composition and the aqueous dissolution medium for a predetermined time; and

(d) determining the amount of analyte in the aqueous dissolution medium.